Environmental Hazard Assessment: Approach

- Review structure, physical-chemical and fate properties, and structural alerts:

  - Physical-chemical properties (e.g., log K_{ow}, water solubility, and MP), presence and position of reactive functional groups, potential for sorption, charge density, minimum cross-sectional diameter of molecules, and mechanisms of toxicity
  - Potential metabolites or degradates (for example, hydrolysis products)
  - Chemical (or degradate) fits within a TSCA New Chemicals Program Category
  - Structural alerts for ecotoxicity (e.g., phenols or esters)

5

Environmental Hazard Assessment: Approach

- Review submitted environmental hazard test data

  - Of the ~1000 new chemicals per year, < 10% have ecological test data
  - If there is submitted test data, is it acceptable?
  - Is the data based on a test guideline or similar method?
    - If not, prepare sufficient rationale for its use in the new chemical program
      - Non-guideline studies may be acceptable if sufficiently conducted and documented
  - Is the test data on the new chemical or an analogue?
    - If an analogue is submitted with test data, provide:
      - Justification for consideration of the analogue
      - Chemical name and CAS numbers of analogue(s)
      - Clear structural representation of the analogue(s)
  - 40 CFR 720.50(a) requires complete toxicity test reports or standard literature citations on the new chemical

    Preference: Chemical-specific test data >> Analogue data > Modeled data

6

Environmental Hazard Assessment: Approach

- Search for appropriate analogues [if hazard endpoints of interest are not fulfilled with measured hazard data]

- Example tools that help with analogue searching (*each operates differently so consult user manuals*)
  - Analogue Identification Methodology (AIM)
    - https://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool
  - ChemID
    - https://chem.nlm.nih.gov/chemidplus/
  - OECD QSAR Toolbox
    - http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm

  Preference: Chemical-specific test data >> Analogue data > Modeled data

7

Environmental Hazard Assessment: Approach

- EPA may need to use modeling to estimate environmental hazard endpoint values [if submitted environmental hazard test data or analogues are not available]

- Ecological Structure Activity Relationships (ECOSAR) Predictive Model
  - Computer program that uses knowledge about chemical structure (log K_{ow} and water solubility) to predict toxicity to aquatic organisms
    - Surrogate species used in standard EPA New Chemicals Program ecotoxicity profile
      - Fish (Vertebrates), Daphnids (Invertebrates), Aquatic Plants (Algae)
  - ECOSAR contains a library of > 120 chemical class-based QSARs[1] for predicting aquatic toxicity overlaid with an expert decision tree for selecting the appropriate chemical class QSAR to use
  - Version 2.0 (released Fall 2017) available for free download at: https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model

  [1]QSARs = Quantitative Structure Activity Relationships

Preference: Chemical-specific test data >> Analogue data > Modeled data   8

Environmental Hazard Assessment: Approach

- Derive acute and chronic concentrations of concern (COC)

  – Harm to the aquatic environment may occur if the COC is exceeded

- Acute COC = Lowest acute toxicity endpoint value ÷ assessment factor[1]

- Chronic COC = Lowest chronic toxicity endpoint value ÷ assessment factor[1]

[1]Assessment factors are used to account for lab-to-field/interspecies variability, as per established EPA/OPPT methods

9

Environmental Hazard Assessment: Approach

- EPA will also consider the following types of information about the chemical substance:

  - Information related to environmental hazards for both short-term (acute) and long-term (chronic) exposures
  - If chemical substances are "difficult-to-test", submitters should consider engaging in a pre-notice communication with EPA prior to toxicity test initiation.
  - Information on % amine-nitrogen content for all relevant chemical substances (e.g., polycationic polymers)

- If the submitter believes that any or all of this information is not applicable or relevant to the new chemical substance, providing an explanation or rationale for why such ecotoxicity information is not relevant for the intended use of the chemical substance could inform EPA's evaluation

10

Environmental Risk Assessment: Approach

- EPA evaluates environmental risk by comparing the acute and chronic COCs to potential environmental concentrations (PEC) of the chemical
  - PEC information is provided in the exposure assessment generated using the E –FAST exposure model

- Evaluation of environmental risk from acute aquatic exposure
  - EPA compares acute COCs directly to the PEC
    - Risk Quotient method
  - Potential for risk from acute exposure exists if the PEC > acute COC

11

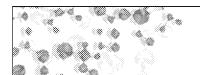# Environmental Risk Assessment: Approach

- Evaluation of environmental risk from chronic aquatic exposure

- If the PEC is greater than the chronic COC, then potential chronic risk may exist (Risk Quotient method).
- Aquatic risk from chronic exposures is further evaluated by determining the number of days per year that the estimated surface water concentration exceeds the chronic COC.
  - Days of exceedance ≤ 20* days/year = risks from chronic exposures would not be expected
  - If the PEC > the chronic COC **and** days of exceedance > 20* days/year = risks may occur from chronic exposures

  *The 20-day criterion is derived from partial life cycle tests (Daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration.

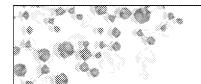12

Environmental Risk Assessment: Approach

- Evaluation of environmental risk from soil/sediment exposures

  - Acute and chronic risks to soil and/or sediment-dwelling organisms are assessed by EPA when physical-chemical and fate properties indicate that the new chemical substance will partition into soils and/or sediments
  - Use and exposure information are also considered when EPA evaluates soil and sediment exposure pathways
  - EPA will consider recommending soil and/or sediment toxicity testing
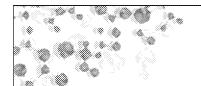
13

EPA Recommends the Submitters Consider:

- Reviewing/refining identified releases to water (many generic assumptions used)
  - Limit releases to water

- Reviewing/refining fate parameter assumptions (e.g., removal rates) of the chemical

- Performing aquatic toxicity testing to refine/empirically determine COCs

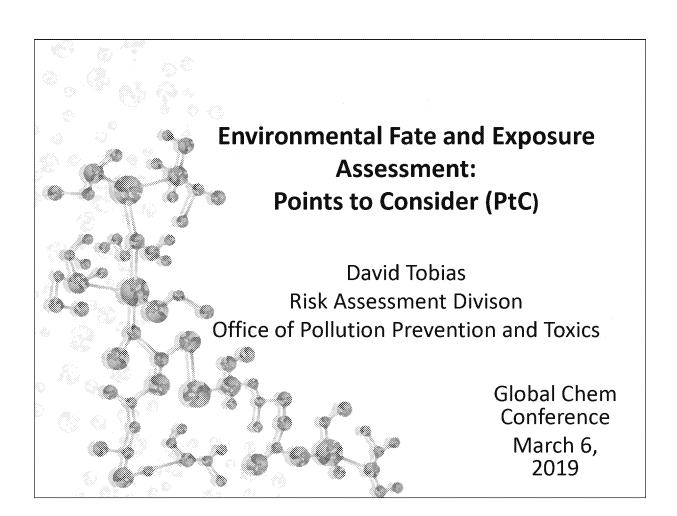- Developing and providing EPA with measured data (e.g., log K_{ow}, NPDES permits) to refine our assessment

14

EPA Recommends the Submitters Consider:

- Understanding your chemical
  - Provide EPA with all available physical/chemical and fate properties

- Submitting all available environmental hazard test data on the new chemical as well as any test data for identified analogues
  - Describe in detail the analogue and its appropriateness

- Chemical-specific test data >> Analogue data > Predictive data (ECOSAR)
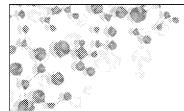
15

EPA Recommends the Submitters Consider:

- Submitting log K_{ow} and water solubility data may significantly refine your assessment
  - In their absence, EPA will use estimated values from EPISuite^{TM}

- Clearly identifying what chemical is being tested (e.g., structure, CASRN, purity) when providing test data with a chemical submission

- Providing documentation developed for the Sustainable Futures program

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Environmental Fate and Exposure Assessment:
Points to Consider (PtC)

David Tobias
Risk Assessment Divison
Office of Pollution Prevention and Toxics

Global Chem
Conference
March 6,
2019

Overview of Presentation

- Exposure Assessment: Overview

- Exposure Assessment
    - Environmental Exposure (non-human)
    - General Population Exposure
        - Drinking water, Groundwater and Air
    - Consumer Exposure

- Environmental Fate Assessment
    - Transport and Partitioning
    - Persistence and Bioaccumulation

- EPA Recommends Submitters Consider (Conclusion)

Note: This presentation is primarily extracted from EPA's Points to Consider document:
https://www.epa.gov/sites/production/files/2018-
06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf

2

Exposure Assessment: Overview

Hazard x Exposure = Risk

- Exposure Assessment
  - Identify exposure pathways <u>and</u> determine relevant concentrations and doses related to these pathways
- Environmental Exposure Assessment
  - Estimate environmental media concentrations based on release mass, receiving water body characteristics and physicochemical characteristics
    - This is combined with environmental hazard information to assess risk
- General Population Exposure and Consumer Exposure Assessment
  - Use estimated environmental media and indoor air concentrations along with behavior patterns (e.g., drinking water consumption per day) to estimate exposure dose for different populations
- Dose commonly stated as mg (chemical) / kg (body weight) / day

3

Environmental Exposure Assessment

- Identify concentrations of the chemical in environmental media, typically using the E-FAST model, for surface water and sometimes sediment

- Calculate an acute environmental exposure for surface water
  - One day surface water concentration based on releases from one site and the 7Q10 flow for the receiving water body
    - 7Q10 : lowest 7 day flow over a period of 10 quarters

- Calculate a chronic environmental exposure for surface water
  - Probabilistic calculation based on the distribution of flows for a site or a group of sites (industrial code)

- Calculate sediment concentrations
  - OPPT uses OPP's Variable Volume Water body Model (VVWM) to calculate sediment concentrations. VVWM is also contained in OPP's Pesticide Water Calculator (PWC)

4

General Population Exposure Assessment

- Exposure to populations living near industrial facilities

  - Drinking Water Exposures
    - Surface water concentrations resulting from water releases in the engineering report
    - Ground water concentrations resulting from landfill releases in the engineering report
  - Inhalation exposures to communities outside the fence line that result from air emissions at industrial sites described in the engineering report

5

Consumer Exposure Assessment

- Evaluate exposure resulting from consumer uses for the chemical

  - Evaluate dermal and inhalation exposures that result from consumer products containing the chemical
  - E-FAST contains a set of 6 consumer exposure models (CEM v 1.2)
    - Built with an evaluative household and pre-programmed consumer behavior patterns for the consumer exposure models
  - Expanded Consumer models in updated version of CEM (CEM v 2.0)
    - New CEM v 2.0 contains 9 additional models
    - Updated consumer behavior patterns
    - Not currently part of E-FAST
    - https://www.epa.gov/tsca-screening-tools/approaches-estimate-consumer-exposure-under-tsca#consumer

6

EPA Recommends Submitters Consider

- Site-specific information (e.g., NPDES) to improve assessment of water releases particularly for small number of industrial sites involved
- Details of incineration at site
  - Hazardous waste incinerator or other characteristics of incineration
  - Measurements for destruction of chemical and/or analogue(s)
- For chemicals with a consumer use
  - Information characterizing the properties of the product
  - Product use characteristics
  - Known consumer behavior patterns that may impact exposure
- Information on the consumer use/behavior characteristics should be accompanied by a citation for the information source or a well-documented rationale
- 40 CFR 720.5 specifies information submission requirements

7

Environmental Fate Assessment: Purpose

- Identify persistence and bioaccumulation score[#]:

	Low	High	Very high	
Persistence	< 2 months	2 to 6 months	≥ 6 months	Half-life
Bioaccumulation	<1000	1000 to 5000	≥ 5000	BCF and/or BAF*

- The BCF/BAF, waste water treatment plant (WWTP) removal and ground water migration values are generated in the fate assessment and used as inputs in the exposure assessment

[#] Scores are generally based on the above criteria, but exceptions can be made for certain chemicals
* Bioconcentration factor (BCF) or bioaccumulation factor (BAF). Generally the higher value is used for determining the bioaccumulation score

8

Environmental Fate Assessment: Approach

- Review structure, physicochemical properties, and structural alerts :

  - Physical-chemical properties, presence and position of functional groups
  - Potential for degradation via biodegradation, hydrolysis or photolysis
  - Structural fragments that may affect metabolism (e.g., esters)
  - Fugacity models based on equilibrium parameters give indication of potential partitioning in WWTPs and the environment

9

Environmental Fate Assessment: Approach

- Review submitted environmental fate test data
  - Most chemical submissions do not have degradation or bioaccumulation data
  - Is the data based on a test guideline or similar method?
    - If not, prepare sufficient rationale for its use in the new chemical program
      - Non-guideline studies may be acceptable if sufficiently conducted and documented
  - Is the test data on the new chemical or an analogue?
    - If an analogue is submitted with test data, provide:
      - Justification for consideration of the analogue
      - Chemical name and CAS numbers of analogue(s)
      - Clear structural representation of the analogue(s)
  - 40 CFR 720.50 (a) requires complete reports or standard literature citations on the new chemical

  Preference: Chemical-specific test data >> Analogue data > Modeled data   10

Environmental Fate Assessment: Approach

- Search for appropriate analogues
- Example tools that help with analogue searching
  - Analogue Identification Methodology (AIM)
    - https://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool
  - ChemID
    - https://chem.nlm.nih.gov/chemidplus/
  - OECD QSAR Toolbox
    - http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm
  - Japan CHEmical Collaborative Knowledge Database (JCHECK)
    - http://www.safe.nite.go.jp/jcheck
  - ECHA Database
    - https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances
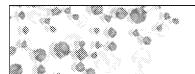
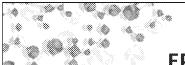Preference: Chemical-specific test data >> Analogue data > Modeled data   11

Environmental Fate Assessment: Approach

- EPA may need to use modeling to estimate environmental fate endpoint values
- Estimation Programs Interface (EPISuite[TM])
    - Computer program that uses collective knowledge about chemical structure to predict the following parameters with QSARs
        - Physicochemical properties
            - KOWWIN estimates the octanol water partitioning coefficient K_{OW}
        - Potential for degradation
            - BIOWIN # 5 & # 6 estimates if a chemical would pass a 301 C MITI ready biodegradation test
        - Bioaccumulation potential
            - BCFBAF estimates a chemical's potential to accumulate in fish tissue based on OECD 305 data and a fish metabolism QSAR
    - Version 4.11 available for free download at:
      https://www.epa.gov/tsca-screening-tools/download-epi-suitetm-estimation-program-interface-v411

[1]QSARs = Quantitative Structure Activity Relationships
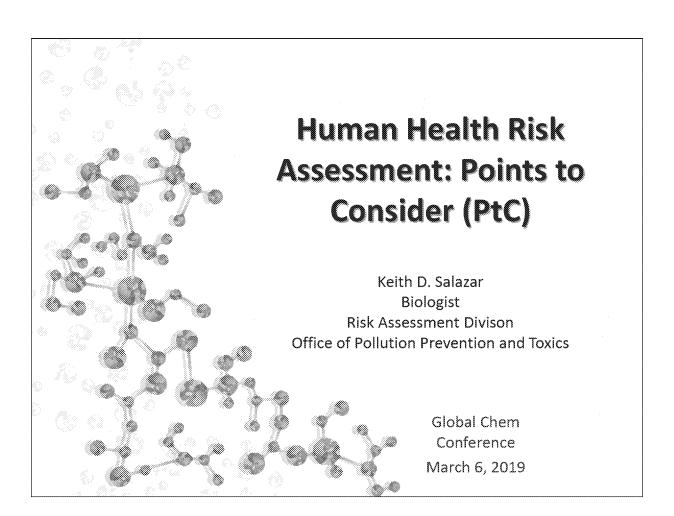Preference: Chemical-specific test data >> Analogue data > Modeled data

EPA Recommends Submitters Consider:

- Measured physicochemical data (e.g., log K_{ow})
- Degradation testing
  - Hydrolysis, photolysis and/or biodegradation data
  - Water, soil and/or sediment studies depending on partitioning behavior
- Bioaccumulation information
  - Consider in-vitro metabolism study for fish - OECD 319
  - Consider dietary exposure for high Log K_{ow} substances (e.g., OECD 305)
- Small-scale WWTP simulation laboratory data (e.g., OECD 303)
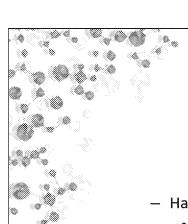
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EPA Recommends Submitter Consider:

- Understand your chemical
  - Provide EPA with all available physical/chemical properties, degradation and bioaccumulation data on the new chemical
    - 40 CFR 720.5 specifies information submission requirements

- Analogue test data
  - Describe in detail the analogue and its appropriateness for the endpoint of concern

- Chemical-specific test data >> Analogue data > Predictive data (EPISuite™)

14

Human Health Risk Assessment: Points to Consider (PtC)

Keith D. Salazar
Biologist
Risk Assessment Divison
Office of Pollution Prevention and Toxics

Global Chem
Conference
March 6, 2019

Purpose

- This presentation will focus on what submitters can do to make the human health risk component of the review process more efficient.

Note: This presentation is primarily extracted from EPA's Points to Consider document: https://www.epa.gov/sites/production/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf   2
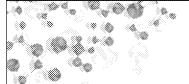
Steps in Human Health Risk Assessment

Hazard x Exposure = Risk

- Hazard Assessment
  - Identify adverse effects <u>and</u> determine concentrations at which these effects occur (concentration-response)
  - Occurs at the Structure Activity Team (SAT) meeting

- Exposure Assessment
  - Calculate the concentration of the chemical in the environment or may come into contact with people

- Risk Characterization
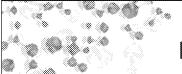 - Compare hazard to exposure

3

Human Health Hazard Assessment: Purpose

- ## Identify/Characterize the following:
  - Absorption by exposure routes based on experimental data or physical-chemical properties or analogue data
  - Hazards associated with the new chemical substance based on data provided in the notification
  - Selection of analogues for informing the identification of potential hazards
  - Hazard key words (e.g., irritation, sensitization, kidney)
  - Relevant routes of exposure (e.g., dermal, inhalation, fish ingestion, and/or drinking water)

4

Human Health Hazard Assessment: Approach

- Review structure, physical-chemical and fate properties, and structural alerts:
  - Physical-chemical properties (e.g., log K_{ow}, water solubility, and MP), presence and position of reactive functional groups, potential for sorption, charge density, minimum cross-sectional diameter of molecules, and mechanisms of toxicity
  - Potential metabolites or degradates (for example, hydrolysis products)
  - Chemical (or degradate) fits within a TSCA New Chemicals Program Category
  - Contains structural alerts for toxicity
  - Identify hazards associated with the category and/or structural alerts

5

Human Health Hazard Assessment: Approach

- Review submitted human health hazard test data
  - Identify hazards associated with or addressed by the submitted data
  - Review hazard information for analogue(s) or from models
  - Review Sustainable Futures submission and all international agency reviews, if applicable
  - Determine if the data are suitable for the identification of a point of departure (e.g., NOAEL, LOAEL, or BMDL) for quantitative risk estimation, or if they can be used qualitative risk estimation
  - Preference: Chemical-specific test data >> Analogue data > Modeled data

6

Human Health Hazard Assessment: Approach

- Search for appropriate analogues
  - Conducted even when data are submitted on the new chemical
  - Address any potential data gaps in the identified hazard
  - Analogues may be identified by EPA chemists, the submitter, or search tools
- Example tools that help with analogue searching (*each operates differently so consult user manuals*)
  - Analogue Identification Methodology (AIM)
    - **https://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool**
  - ChemID
    - **https://chem.nlm.nih.gov/chemidplus/**
  - OECD QSAR Toolbox
    - **http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm**

7

Human Health Risk Assessment: Overall Approach

- Risk characterization is part of the risk assessment and takes the form of a conclusion about the chemical substance's potential for health and environmental risk.

- It embodies the effects of potential concern, the route and magnitude of expected exposure, and the population estimated to be exposed.

8

Human Health Risk Assessment: Quantitative Approach

- If a point of departure (POD) is identified during the human health hazard/toxicity data review, then risks are quantified.

- Risks are generally calculated using the Margin of Exposure approach; occasionally, data are sufficient to use other approaches.

- The MOEs are then compared to a benchmark MOE to determine if potential risks of concern are present.

- Potential risks are identified if the calculated MOE is below the benchmark MOE.

9

Human Health Risk Assessment: Quantitative Approach

- The benchmark MOE is obtained by multiplying the total uncertainty factors (UFs) associated with each POD.

- These UFs typically include:

    1. The variation in susceptibility among members of the human population (*i.e.*, inter-individual or intraspecies variability or UFH = default of 10),

    2. The uncertainty in extrapolating animal data to humans (*i.e.*, interspecies uncertainty or UFA = default of 10)

    3. An additional UF may be added if the POD is based on a LOAEL, rather than a NOAEL (*i.e.*, LOAEL-to-NOAEL extrapolation or UFL = 10)

- Hence, UFs are typically 100 or 1000; occasionally 10 is used when PODs derived from human data are used

10

Human Health Risk Assessment: Quantitative Approach

- If risks are identified using default screening assumptions, EPA may refine the risk calculations based on:
  - Absorption
  - If relevant, % of chemical substance that is comprised of structural alert for hazard.
  - e.g., if the hazard identified for a polymer is due to a particular moiety that is 2% of the molecular weight of the polymer, then the exposure may be adjusted to 2% of the total estimated dose and risk estimated accordingly.

11

Human Health Risk Assessment: Quantitative Approach

- In some cases, EPA has estimated exposures for a new chemical substance, under the conditions of use; however, there was no hazard information available on the new chemical substance, including no structural alerts or acceptable analogues with test data.

- Under these circumstance, EPA cannot perform a reasoned evaluation of potential risks and will generally request testing on the new chemical substance, unless exposures for the relevant route(s) can be eliminated or mitigated.

12

Human Health Risk Assessment: Qualitative Approach

- In some cases, hazards are identified based on a structural alert, but data are not available to derive a quantitative POD (a benchmark MOE cannot be quantified).

- In such a case, if there are populations that may be exposed, EPA may qualitatively identify carcinogenicity as a potential risk and consider whether data are sufficient for a reasoned evaluation.
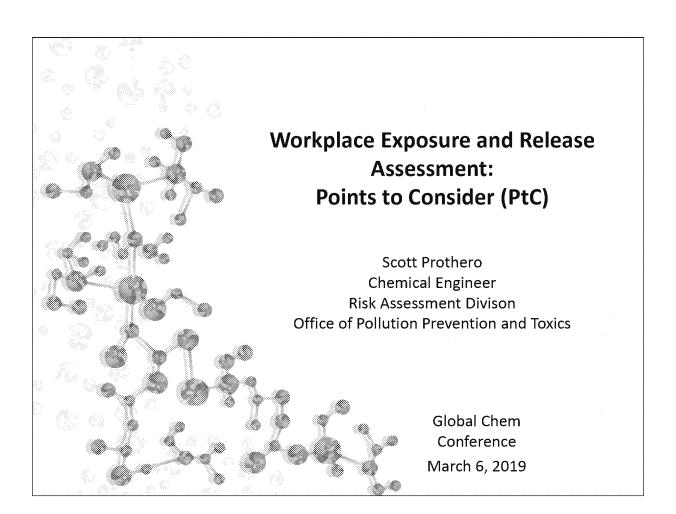
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EPA Recommends Submitters Consider:

- Providing an explanation or rationale for why any toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation.

- Submitters should consider whether the new chemical substance has been submitted to/reviewed by another international agency.

- Submitters should consider whether the structure of the new chemical substance has any structural alerts.

- Submitted particle size/droplet size information for the new chemical substance would aid the assessment of respirability.

14

EPA Recommends Submitters Consider:

- Submitters should consider whether *in silico, in vitro,* or other non-vertebrate test information are appropriate for evaluating their chemical substance.

- Submitters should consider whether *in silico, in vitro,* or other non-vertebrate test information are appropriate for evaluating their chemical substance.

- Provide justification for consideration of the analogue for the endpoint(s) identified.

- Provide chemical name and CAS numbers of all analogues .

- Provide clear structural representation of the analogue substance(s).

- Provide full studies on the analogues, if available, to better ensure efficient consideration by EPA.   15

Workplace Exposure and Release Assessment: Points to Consider (PtC)

Scott Prothero
Chemical Engineer
Risk Assessment Divison
Office of Pollution Prevention and Toxics

Global Chem
Conference
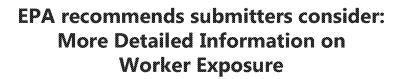March 6, 2019

Overview of Presentation

- This presentation will focus on what submitters can do to support better review in terms of Workplace Exposure and Release Assessments.
- Not all of the suggestions in this presentation may be relevant for your new chemical substance.

Note: This presentation is primarily extracted from EPA's Points to Consider document: https://www.epa.gov/sites/production/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf

2

EPA recommends submitters consider: More Detailed Information on Worker Exposure

- Provide detailed descriptions of the manufacturing, processing and use operations for the intended use(s) and activities that may result in worker exposure.
  - Open or closed?
  - Conducted at ambient or elevated temperatures?
  - Batch or continuous?
  - Spray or non-spray?
  - What is the frequency and duration of each worker activity?
  - How (dermal and/or inhalation) and during which activities is worker exposure expected?
  - If worker exposure is not expected, provide specific explanation and rationale
  - How many workers are exposed during these activities?

3

EPA recommends submitters consider: More Detailed Information on Worker Exposure
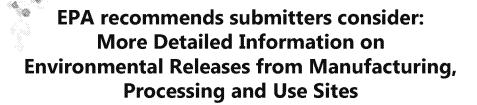
- Describe the specific type of personal protective equipment (PPE) that will be used at the manufacturing site and, to the extent known, at processing and use sites.
  - What kind of gloves (e.g., material composition, name/model number)?
  - What kind of protective clothing and goggles (e.g., name/model number)?
  - What kind of respirator (e.g., name/model number, cartridge type, assigned protection factor (APF))?

4

**EPA recommends submitters consider:
More Detailed Information on
Worker Exposure**
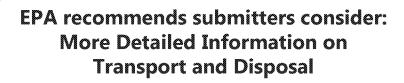
- If the new chemical substance is manufactured, processed, or used as a solid or powder, indicate whether the manufacture, processing, and/or use of the new chemical substance is expected to result in suspended particles (also referred to as dust) in air.
  - Include supporting measured data on particle size distribution and/or type of solid material (e.g., powder, wet cake with 30% moisture content, paste, or slurry).

- Include any Safety Data Sheet (SDS) or Materials Safety Data Sheet (MSDS).

5

EPA recommends submitters consider:
More Detailed Information on
Environmental Releases from Manufacturing,
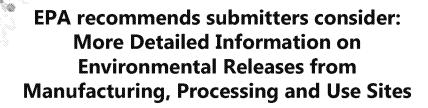**Processing and Use Sites**

- How often is the equipment cleaned (e.g., every day, after every batch, once a year)?
- What is used to clean the equipment (e.g., water, solvent, steam)?
- For all releases, you are required to provide estimates of the amount and the frequency of releases. Be sure to include detailed information on the basis for each estimate.
- How is waste (including cleaning and process waste) disposed (e.g., on-site waste water treatment, POTW, venting, incineration, landfill, etc.)

EPA recommends submitters consider:
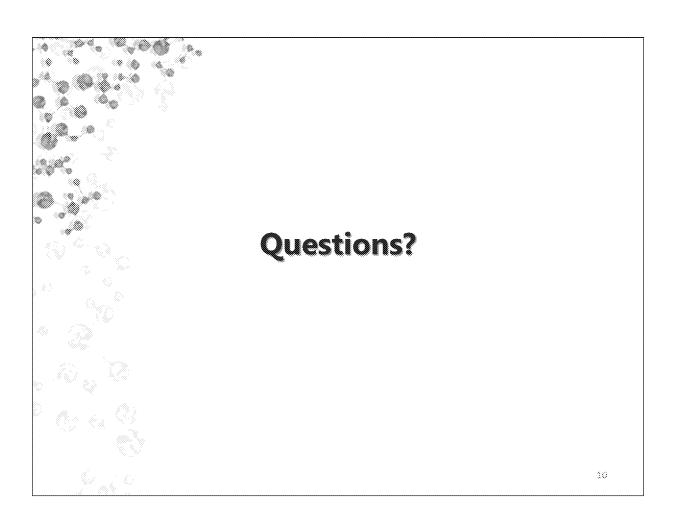## More Detailed Information on
Transport and Disposal

- Describe the transport container type, capacity and container cleaning procedure and frequency including, for example, the following information:
  - Five 5,000-gallon trucks used to store/transport the chemical substance are dedicated and rinsed once every 20 deliveries.
  - The rinsate that contains the chemical substance is put down the drain, incinerated, etc.
  - The cleaning and disposal of the transport containers are performed by the submitter on site.
- If the containers are cleaned or disposed of off-site, provide available information including the cleaning methods, frequency of cleaning, and estimated amount of new chemical substance released per cleaning.

7

**EPA recommends submitters consider:
More Detailed Information on
Environmental Releases from
Manufacturing, Processing and Use Sites**

- Provide the National Pollution Discharge Elimination System ("NPDES") permit numbers (i.e., non-storm water permit numbers) for WWTFs at a manufacturing site(s), a known processing site(s), and a known use site(s), or the NPDES permit numbers for the POTWs receiving wastewater from the facility(ies).
  - ○ Specify the type of wastewater treatment technologies used at the facility(ies).
  - ○ Provide any removal efficiency information for onsite treatment unit operations. Indicate whether the information estimated or measured.

8

EPA recommends submitters consider: More Detailed Information on Environmental Releases from Manufacturing, Processing and Use Sites

- Provide the Clean Air Act operating permit numbers for facilities with expected releases to air.
  - Specify the type of air pollution control technologies used at the facility(ies).
  - Provide any removal efficiency information for onsite treatment unit operations. Indicate whether the information is estimated or measured and provide supporting information.
  - Is the facility under a Leak Detection and Repair program (related to the monitoring and management of fugitive releases)? If "yes," describe the program.

9

Questions?

10

From:	Schweer, Greg [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FE412A2024B4F548EEB02E7E931F484-GSCHWEER]
Sent:	2/27/2019 7:43:32 PM
To:	Franz, Christina [Christina_Franz@americanchemistry.com]
CC:	Pierce, Alison [Pierce.Alison@epa.gov]; Starr, Richard [Richard_Starr@americanchemistry.com]; Brozena, Sarah
	[Sarah_Brozena@americanchemistry.com]; Blanco, Susan [Susan_Blanco@americanchemistry.com]
Subject:	RE: Names for the PMN Session
Attachments:	Salazar.jpg; bio-salazar.docx

Christina,

Picture and bio for Keith Salazar are attached. Still waiting on David Tobias for his bio and pic.

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Wednesday, February 27, 2019 2:35 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala
<Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard
<Richard_Starr@americanchemistry.com>; Brozena, Sarah <Sarah_Brozena@americanchemistry.com>; Blanco, Susan
<Susan_Blanco@americanchemistry.com>; Blair, Susanna <Blair.Susanna@epa.gov>
Subject: RE: Names for the PMN Session

Thank you, Greg. I believe so, but will check.

Christina Franz

Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second St., NE
Washington, D.C. 20002
202-249-6406 (o)
301-580-6562 (c)
Christina_Franz@americanchemistry.com

From: Schweer, Greg [mailto:Schweer.Greg@epa.gov]
Sent: Tuesday, February 26, 2019 8:27 AM
To: Franz, Christina <Christina_Franz@americanchemistry.com>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala
<Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard
<Richard_Starr@americanchemistry.com>; Brozena, Sarah <Sarah_Brozena@americanchemistry.com>; Blanco, Susan
<Susan_Blanco@americanchemistry.com>; Blair, Susanna <Blair.Susanna@epa.gov>
Subject: RE: Names for the PMN Session

Christina,

Attached are the bios and pics for three of us (Greg Schweer, Jeff Gallagher, and Scott Prothero). I believe that Rebecca
Edelstein already sent her bio and pic to you. I am awaiting bios/pics from Keith Salazar and David Tobias.

Our six presentations are currently being reviewed by the OCSPP IO. Hopefully, that review will be completed soon.

I received a registration confirmation from ACC Meeting Services. I assume that the other five EPA folks for this session will also be registered. Correct assumption?

From: Schweer, Greg
Sent: Monday, February 25, 2019 4:24 PM
To: 'Franz, Christina' <Christina_Franz@americanchemistry.com>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard <Richard_Starr@americanchemistry.com>; Brozena, Sarah <Sarah_Brozena@americanchemistry.com>
Subject: RE: Names for the PMN Session

Christina,

Thanks for the followup note. I just put out a request for the remaining bios/pictures from three of the presenters; I already have the other three.

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Monday, February 25, 2019 3:26 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard <Richard_Starr@americanchemistry.com>; Brozena, Sarah <Sarah_Brozena@americanchemistry.com>
Subject: RE: Names for the PMN Session

We'll make it work.

Can everyone who has not done so already please send a brief bio and headshot to me as soon as possible?

Thanks very much.

Christina Franz

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700 Second St., NE
Washington, D.C. 20002
202-249-6406 (o)
301-580-6562 (c)
Christina_Franz@americanchemistry.com

From: Schweer, Greg [mailto:Schweer.Greg@epa.gov]
Sent: Wednesday, February 20, 2019 4:04 PM
To: Franz, Christina <Christina_Franz@americanchemistry.com>
Cc: Pierce, Alison <Pierce.Alison@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>; Starr, Richard <Richard_Starr@americanchemistry.com>; Brozena, Sarah <Sarah_Brozena@americanchemistry.com>
Subject: Re: Names for the PMN Session

Christina,

I am not certain where the communications wet astray. I was notified the week we returned from the shutdown that I was responsible for putting together the 2-hour training workshop. No mention was made to me that Kelly was going to be part of the panel. So, we quickly pulled together a team to present what we thought would address the scope of the session. It was not until I rec'd your invitation on Feb 12 for a conference call that I saw Kelly as part of the package. I thought that she perhaps was going to be the Moderator for the session.

Nonetheless, I just spoke with Tala Henry. All of our six presentations have been drafted and are being reviewed by OGC. We think that we can work still use all six EPA presenters but limit their presentations to 12 minutes each, on average, and thus ensure that Kelly has the 25 minutes you have allocated in the proposal below. In the first session, I will lead off, followed by Scott Prothero (worker exposure and environmental release assessment), David Tobias (fate, general population exposure, and consumer exposure), and Jeff Gallagher (eco hazard & risk). Keith Salazar (human health hazard & risk) will lead off the 2nd session, followed by Rebecca Edelstein, and then Kelly.

Sound OK to you?

From: Franz, Christina <<u>Christina_Franz@americanchemistry.com</u>>
Sent: Wednesday, February 20, 2019 1:22 PM
To: Schweer, Greg
Cc: Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance; Starr, Richard; Brozena, Sarah
Subject: RE: Names for the PMN Session

This was the proposal Kelly and I discussed:

9:30 AM - 10:30 AM   PMN Workshop: Session 1
Greg Schweer, EPA (25 mins) – TSCA Section 5 Updates, new regulatory determinations, and introduction to the new chemical review process
David Tobias, EPA (25 mins) – Introduction of the Points to Consider Document and outline of additional information to provide with new chemical submissions
Q & A – 10 minutes

10:45 AM - 11:45 AM   PMN Workshop: Session 2
Rebecca Edelstien, EPA (25 minutes) – PreNotice Communication process and how to coordinate with the Agency post-notification
Kelly Mayo, knoell USA (25 minutes) – Tips for preparing notification packages and strategies for supply chain communication
Q & A – 10 minutes

From: Franz, Christina
Sent: Wednesday, February 20, 2019 12:53 PM
To: Schweer, Greg
Cc: Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance; Starr, Richard; Brozena, Sarah
Subject: RE: Names for the PMN Session

Hello Greg:

I am not quite sure what happened in the communications between Richard Starr, Alison Pierce, Hans Scheifele and/or communications between Alison, Hans, and you, but let me try at least to explain my perspective on my own confusion and how I would propose to resolve the confusion.

The panel description that I was given on the Global Chem agenda identifies you and two other EPA presenters--David Tobias and Rebecca Edelstein. The fourth presenter was Kelly Mayo Bean. Kelly's organization is a sponsor, which is expensive and afforded her the opportunity to cover about 40 minutes of the presentation. That is why when I sent out the meeting invite for our discussion a few weeks ago, I sent it to you, David, Rebecca, and Kelly. I was very surprised when we had the call that you had as many people from EPA on the phone and all had a planned presentation. However, I didn't feel I was in a position to say much about it at the moment as a stand-in as moderator because I wasn't certain I had all the facts at my disposal. However, I was surprised by your comment, Greg, during the call that you did not know Kelly was a part of the panel.

Once our call was completed, it became clear the Kelly would not really have much of an opportunity to speak. This is posing a problem for her company as a sponsor. It appears to me, albeit from the outside since I am not part of the organizing team, that a possible miscommunication happened at EPA--largely because Greg said that he did not know Kelly was supposed to be a part of the panel. If I am incorrect about that, my apologies, I am only trying to piece this together. I think the only right thing to do is to return to the original format and divide the presentation up accordingly.

I had a phone conversation with Kelly and made notes on what that division might look like, but I am not in the office this week and do not have it in front of me. I would have to write to her and get that breakout by email. Perhaps it is readily apparent to you knowing her background and those of David and Rebecca, but it is not to me--apologies for that. I do recall that Kelly suggested perhaps the others from EPA you wanted to present could be in attendance to answer questions that the audience might have regardig their areas of expertise.

Does this make sense to folks?

I have copied Richard Starr and Sarah Brozena on this email as well--Richard because he is ACC's Global Chem organizer and Sarah because she was on our panel call with me, although we had agreed that I would moderate the panel.

In closing, it is a shame there has been a mixup with this session. I certainly don't want to offend anyone or cast any aspersions--these things happen sometimes. I just think returning to the original plan is the correct thing to do for all concerned.

Christina

From: Schweer, Greg [Schweer.Greg@epa.gov]
Sent: Wednesday, February 20, 2019 11:29 AM
To: Franz, Christina
Cc: Pierce, Alison; Scheifele, Hans; Henry, Tala; Wormell, Lance
Subject: Re: Names for the PMN Session

Christina,

This is an interesting turn of events. How do you and Kelly want to schedule her 40 minutes? We will need to shorten our presentations (or at least skip slides) or shorten the Q&A time.

From: Starr, Richard <Richard_Starr@americanchemistry.com>
Sent: Wednesday, February 20, 2019 10:55 AM
To: Scheifele, Hans
Cc: Pierce, Alison; Franz, Christina; Schweer, Greg
Subject: Re: Names for the PMN Session

Hi Hans, thanks for the note - I hope you're enjoying the light snow today. This matter is probably better resolved over the phone, but the weather is giving us little choice.

As happens sometimes, I think there may have been a mix up at some point. Kelly is with Knoell consulting, and they have paid for a sponsorship which encompasses a 40 minute presentation, so we will provide her that time, whether it is 20 minutes at the end of each half of the session (which may have been a source of the misunderstanding), or all at once. That is up to the group to split up, of course.

As I mentioned on the phone, the total time is 120 minutes (two one hour sessions with a 15 minute break in between), so the remaining 80 minutes is free to be split up however the group decides.

Sent from my iPhone

On Feb 19, 2019, at 10:06 PM, Scheifele, Hans <Scheifele.Hans@epa.gov> wrote:

> Hi Richard,
>
> I'm following up on our conversation and email last Friday. Sorry for not getting back to you until now. I spoke with Greg Schweer and understand that he, Christina and others, including Kelly I believe, discussed the details last Wednesday and it was agreed that Kelly would have 20 minutes (at the end of the session as I understand it). I need to defer to the decisions of the planning group as discussed and agreed to last week. I've cc'ed Greg here if you have more questions. If I've misunderstood something Greg can clarify and/or discuss details further with Christina and you.
>
> Thanks,
> Hans
>
> On Feb 14, 2019, at 1:36 PM, Starr, Richard <Richard_Starr@americanchemistry.com> wrote:
>
>> Hi Alison (and Hans),
>>
>> Thank you for providing me with these names.
>>
>> We truly appreciate the interest in this session, though we'd like to ensure that the format leaves room for the non-EPA presenter on the panel.
>>
>> I'd like to reduce the number of formal presentations per hour to the original format (unless staff would like to tag in/out). This would ensure that each speaker/presenter could average about 20 minutes per hour including questions

(Kelly Mayo's presentation is about 40 minutes, and would thus count for two slots). Any additional folks that do not make formal presentations could certainly be made available for Q&A portions of the session.

I've copied Christina Franz, our moderator for the session, to clarify anything I missed, and help answer any questions about the format we're looking for.

Thank you!

Richard Starr | American Chemistry Council
Manager, Regulatory & Technical Affairs
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www.americanchemistry.com

From: Pierce, Alison [mailto:Pierce.Alison@epa.gov]
Sent: Wednesday, February 13, 2019 3:12 PM
To: Starr, Richard
Subject: Names for the PMN Session

Richard – Per discussion, here's our current slew of folks who will be helping out on the PMN session:

- Greg Schweer
- Rebecca Edelstein
- David Tobias
- Jeff Gallagher
- Keith Salazar
- Scott Prothero

Best,
Alison

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Keith D. Salazar has worked as a biologist with the United States Environmental Protection Agency for the past 10 years. During his tenure with the Agency, he has worked in the laboratories at Research Triangle Park, NC studying the immunotoxic effects of Libby asbestos. He later worked as a chemical manager with IRIS program in Washington, D.C. developing risk assessments on several chemicals including benzo[a]pyrene, tert-butanol, ETBE, and RDX. He has represented the Agency in national and international panels and most recently contributed to the IARC monograph update of benzene. In his current role, he develops human health risk assessments for new chemicals within the Office of Pollution Prevention and Toxics Risk Assessment Division (RAD). He holds degrees from West Virginia University and The University of the South.